Bimekizumab Leads to Sustained Flare-Free Status in Moderate to Severe Hidradenitis Suppurativa: 3-Year Data from BE HEARD EXT

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Objective

To assess flare outcomes in all, or baseline Hurley stage II or III patients, with moderate to severe hidradenitis suppurativa (HS) treated with bimekizumab (BKZ) over 3 years (148 weeks).

Synopsis

- HS is characterized by nodules, abscesses, and draining tunnels (DT), with acute exacerbations of symptoms known as "flares".[1,2]
- Timely, effective disease management is important to reduce the frequency of flares.[1]
- BKZ is a humanized IgG1 monoclonal antibody that selectively inhibits interleukin (IL)-17A and IL-17F.[3]

Methods

- Data were pooled from BE HEARD I&II and their open-label extension BE HEARD EXT (BHEXT) (**Figure 1**).[4,5]
- Patients randomized to receive BKZ 320 mg from baseline in BE HEARD I&II who entered BE HEARD EXT were included (BKZ Total group); data were also reported by baseline Hurley stage.
- Flare data were collected at scheduled clinic visits. Data are reported as observed case (OC).
- Flare was defined as a ≥25% increase in abscess and inflammatory nodule (AN) count versus baseline with an absolute increase in AN count of ≥2.
- Flare outcomes were assessed in patients with moderate to severe HS treated with BKZ over 3 years (to Week 148; **Summary**). Flare outcomes reported were:
  - The cumulative proportion of patients who remained flare-free (no observed flares at any visit up to and including the given timepoint);
  - The proportion of patients with a flare at a given visit (flare rates reported at a single point).

Results

- 556 patients randomized to BKZ at baseline in BE HEARD I&II completed Week 48 and entered BE HEARD EXT.
- Baseline demographics and clinical characteristics of patients are presented in the **Table**.
- At Week 48, the cumulative proportion of patients who were flare-free was 83.8% (466/556). This remained similar at Week 96 (83.7% [374/447]) and then increased by Week 148 with 86.1% (316/367) of patients remaining flare-free (**Figure 2A**).
- High proportions of patients remaining in the study were reported flare-free regardless of Hurley stage in Year 3 (**Figure 2B**).
- At Week 48, 2.2% (12/556) of patients experienced a flare. This decreased to 0.9% (4/447) at Week 96 and decreased further by Week 148, at which point no patients (0/367) experienced a flare (**Figure 3A**).
- Numerically lower flare rates were observed in patients who were Hurley stage II versus those who were Hurley stage III at any given visit through Year 1 (**Figure 3B**).

Conclusions

Most patients treated with bimekizumab who stayed in the study remained flare-free at all visits through 3 years.

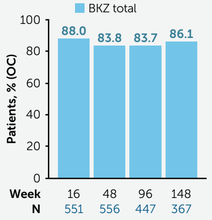
Bimekizumab-treated patients who were Hurley stage II experienced numerically lower flare rates through Year 1 versus those who were Hurley stage III. In Year 3, low flare rates were achieved by all patients remaining in the study, regardless of Hurley stage.

These data suggest that initiating bimekizumab therapy in Hurley stage II patients may lead to more rapid control of inflammatory flares.

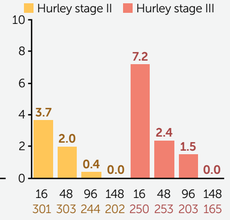
Summary

Flare outcomes were assessed in patients with **moderate to severe HS** treated with **bimekizumab** over 3 years.

Cumulative proportion of patients remaining flare-free[a]



Proportion of patients experiencing a flare[b]



Most **bimekizumab-treated** patients **remained flare-free** at scheduled clinic visits through 3 years and **did not experience a flare** at Year 3, regardless of baseline Hurley stage.

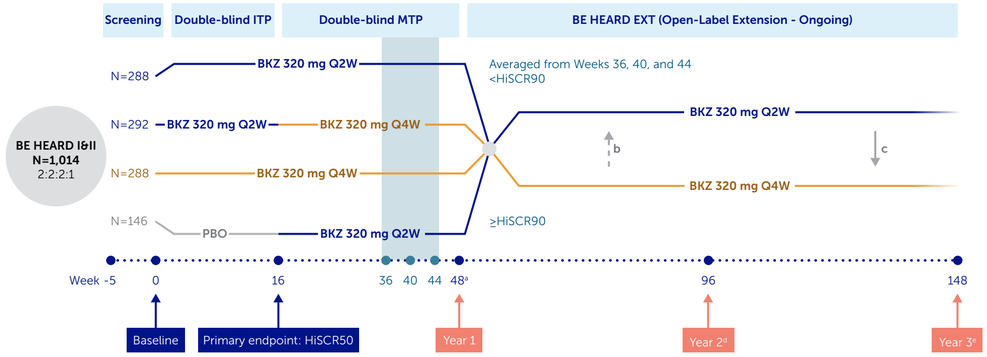
[a] No observed flares at any visit up to and including the given timepoint. **[b]** Flare rates reported at a single point.

Table Baseline characteristics

	BKZ Total N=556	Hurley stage II[a] N=303	Hurley stage III[a] N=253
Age, years, mean (SD)	36.3 (12.2)	36.5 (12.3)	36.1 (12.0)
Sex, female, n (%)	299 (53.8)	172 (56.8)	127 (50.2)
Racial group, White, n (%)	448 (80.6)	258 (85.1)	190 (75.1)
Smoking status, current, n (%)	260 (46.8)	145 (47.9)	115 (45.5)
BMI, kg/m^2, mean (SD)	32.5 (7.8)	32.6 (8.1)	32.5 (7.5)
Duration of HS, years, mean (SD)	7.4 (7.1)	7.3 (7.4)	7.5 (6.9)
DLQI total score, mean (SD)	11.0 (6.8)	10.1 (6.5)	12.2 (7.0)
AN count, mean (SD)	16.9 (18.5)	14.7 (18.8)	19.6 (17.9)
DT count, mean (SD)	3.8 (4.3)	2.0 (2.3)	5.9 (5.1)
Hurley stage,[b] n (%)			
II	303 (54.5)	303 (100.0)	0 (0.0)
III	253 (45.5)	0 (0.0)	253 (100.0)

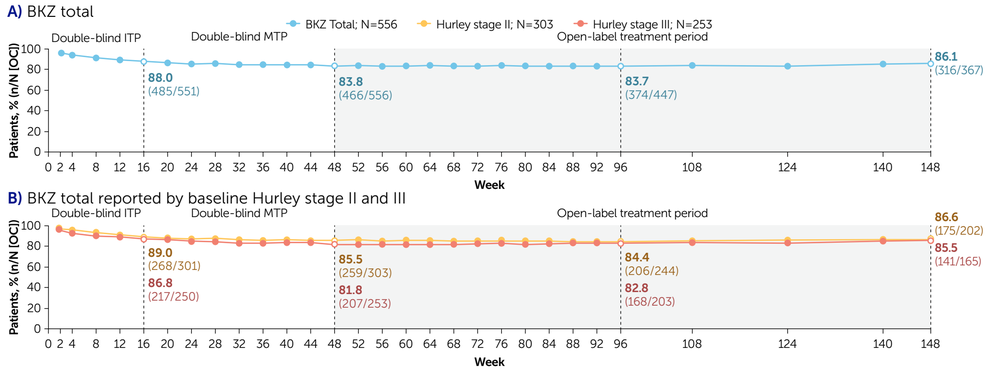
[a] Refers to baseline Hurley stage; **[b]** This refers to the worst overall Hurley stage derived from the Hurley stages recorded across all anatomical regions.

Figure 1 Study design



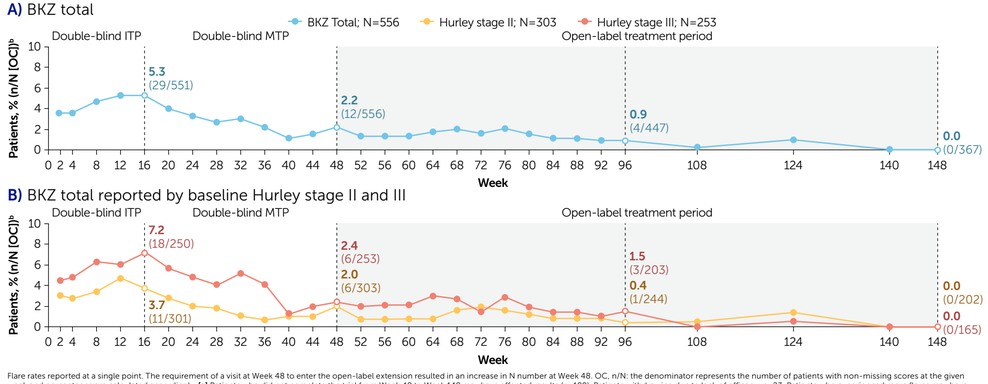
[a] Patients who completed Week 48 of BE HEARD I&II could enroll in BE HEARD EXT and receive open-label BKZ Q2W or BKZ Q4W based on HiSCR90 responder status using the average lesion counts from Week 36, Week 40, and Week 44 of BE HEARD I&II. **[b]** Patients receiving BKZ 320 mg Q4W in BE HEARD EXT who could not sustain an average improvement from baseline in AN count of >90% over any 8-week period or achieve >75% improvement from baseline in AN count at any single visit, could have their dose increased to Q2W at investigator discretion. **[c]** Following approval of a protocol amendment in the third year, all BE HEARD EXT patients were to receive BKZ Q4W. **[d]** Cumulative 2-year data (48 weeks in BE HEARD I&II and 48 weeks in BE HEARD EXT). **[e]** Cumulative 3-year data (48 weeks in BE HEARD I&II and 100 weeks in BE HEARD EXT).

Figure 2 Cumulative proportions of patients remaining flare-free over 3 years[a]



Remaining flare-free: no observed flares at any visit up to and including the given timepoint. The requirement of a visit at Week 48 to enter the open-label extension resulted in an increase in N number at Week 48. OC, n/N: the denominator represents the number of patients with non-missing scores at the given week and percentages are calculated accordingly. **[a]** Patients who did not complete the trial from Week 48 to Week 148 may have affected results (n=189). Patients withdrawing due to lack of efficacy: n=23. Patients who experienced more flares may have been more likely to withdraw.

Figure 3 Proportions of patients experiencing a flare at a given visit over 3 years[a]



Flare rates reported at a single point. The requirement of a visit at Week 48 to enter the open-label extension resulted in an increase in N number at Week 48. OC, n/N: the denominator represents the number of patients with non-missing scores at the given week and percentages are calculated accordingly. **[a]** Patients who did not complete the trial from Week 48 to Week 148 may have affected results (n=189). Patients withdrawing due to lack of efficacy: n=23. Patients who experienced more flares may have been more likely to withdraw. **[b]** Due to the small range of percentage values, the Y-axis range is 0–10%.

AN: abscess and inflammatory nodule; **BKZ:** bimekizumab; **BMI:** body mass index; **DLQI:** Dermatology Life Quality Index; **DT:** draining tunnel; **HiSCR50/90:** ≥50%/90% reduction from baseline in total abscess and inflammatory nodule count with no increase from baseline in abscess or draining tunnel count; **HS:** hidradenitis suppurativa; **IL:** interleukin; **ITP:** initial treatment period; **MTP:** maintenance treatment period; **OC:** observed case; **PBO:** placebo; **Q2W:** every two weeks; **Q4W:** every four weeks; **SD:** standard deviation.

References: [1]Masson R et al. Skin Appendage Disord 2024;10:224–8; [2]Kirby JS et al. Br J Dermatol 2020;182:24–8; [3]Adams R et al. Front Immunol 2020;11:1894. [4]Kimball AB et al. Lancet 2024;403:2504–19 (NCT04242446, NCT04242498); [5]BE HEARD EXT (NCT04901195): www.clinicaltrials.gov/study/NCT04901195. **Author Contributions:** Substantial contributions to study conception/design, or acquisition/analysis/interpretation of data: **SD**, **HBN**, **ZR**, **SY**, **PFP**, **BL**, **CC**, **NT**, **AM**; Drafting of the publication, or reviewing it critically for important intellectual content: **SD**, **HBN**, **ZR**, **SY**, **PFP**, **BL**, **CC**, **NT**, **AM**; Final approval of the publication: **SD**, **HBN**, **ZR**, **SY**, **PFP**, **BL**, **CC**, **NT**, **AM**. **Author Disclosures: SD:** Speaker for AbbVie, Novartis, and UCB; consultant for AbbVie, Novartis, and UCB; research grants from AbbVie, Incyte, Insmed, MoonLake Immunotherapeutics, Pfizer, Regeneron, Sanofi, and UCB. **HBN:** Consulting fees from AbbVie, Incyte, MoonLake Immunotherapeutics, Novartis, Sonoma Biotherapeutics, and UCB; holds shares in Radera Inc.; Editorial Board Member for JAMA Dermatology; Vice President of the US Hidradenitis Suppurativa Foundation. **ZR:** Investigator, speaker, and/or advisor for AbbVie, Almirall, Amgen, Avene, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Cellitrion, CeraVe, Eli Lilly and Company, Incyte, Janssen, La Roche-Posay, LEO Pharma, Novartis, Pfizer, Regeneron, Sanofi, and UCB; personal fees for attending meetings or for travel from AbbVie, Almirall, Amgen, Bristol Myers Squibb, Cellitrion, Eli Lilly and Company, Janssen, Novartis, Pfizer, Sanofi, and UCB. **SY:** Consulting for Kaken Pharmaceutical, received travel grants or honoraria from AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Maruho, Sanofi, TAIYO Pharma, and UCB; department participated in trials for AbbVie, Boehringer Ingelheim, Eli Lilly and Company, Janssen, Kaken Pharmaceutical, Kyowa Kirin Corporation, Novartis, Sanofi, and UCB. **PFP:** Served on advisory boards for AbbVie, Amgen, Boehringer Ingelheim, Eli Lilly and Company, Johnson & Johnson, L'Oréal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, and UCB; has given educational lectures for AbbVie, Amgen, Eli Lilly and Company, Galderma, Johnson & Johnson, L'Oréal, LEO Pharma, Merck, Merck Sharp & Dohme, Novartis, Pfizer, Pierre Fabre, UCB, and Zuellig Pharma; has received research funding from Pfizer; has conducted clinical trials for AbbVie, Aksobio, Alumis, Amgen, Apogee, AstraZeneca, Boehringer Ingelheim, Bristol Myers Squibb, CellDex, CSL, Chugai, Eisai, Eli Lilly and Company, Galderma, Incyte, Johnson & Johnson, Jiangsu Hengrui, KoBioLabs, Merck, Merck Sharp & Dohme, miRagen, Moderna, Nektar, Novartis, OncoSec, Pfizer, Regeneron, Sanofi, and UCB. **BL**, **CC**, **NT:** Employees and shareholders of UCB. **AM:** Received honoraria and/or travel grants and/or acted as an advisory board member for AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Company, Janssen, LEO Pharma, L'Oréal, Novartis, Sanofi, Legit Health, and UCB; worked as a principal investigator in clinical trials supported by AbbVie, Bristol Myers Squibb, Eli Lilly and Company, Galderma, Janssen, Legit Health, Novartis, Sanofi, and UCB. **Acknowledgments:** We would like to thank the patients and their caregivers in addition to all the investigators and their teams who contributed to this study. The authors acknowledge Susanne Wiegratz, MSc, UCB, Monheim am Rhein, Germany for publication coordination, Sarah Johnson, MSci, Costello Medical, Manchester, UK for medical writing support and editorial assistance, Emily Johnson, BSc, Costello Medical, London, UK, for editorial assistance, and the Costello Medical Creative team for design support. This study was funded by UCB. All costs associated with development of this poster were funded by UCB.

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